

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Andrew SAXON, et al.

Application Serial No: 09/770,169

Filed: January 26, 2001

For: **Immunoglobulin Class Switch  
Recombination**

) Confirmation No.: 8085

)

) Group Art Unit: 1644

)

) Examiner: Schwadron, Ronald B.

)

) **Attorney Docket No.: 39754-  
0531A**

)

**EXPRESS MAIL LABEL NO. EL 977 611 895**

**Date Mailed: January 5, 2005**

**PETITION TO WITHDRAW THE HOLDING OF ABANDONMENT  
UNDER 37 C.F.R. 1.181**

MS: Petitions  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

In connection with the above-identified patent application, a Notice of Abandonment was mailed on December 8, 2004. According to the Notice of Abandonment, the application is abandoned in view of Applicants' failure to timely file a proper reply to the Office communication dated March 4, 2004.

Applicants submit that the Notice of Abandonment was issued in error.

Enclosed herewith are (i) substitute sequence listing, dated January 4, 2005; (ii) sequence listing statement dated January 5, 2005; and (iii) copy of Applicants' preliminary Amendment filed August 31, 2004.

**STATEMENT OF FACTS**

On March 4, 2004, the PTO issued a "Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures". The Notice indicates that "[n]o sequence listing has been submitted for the sequence recited in page 15, line 24 of the specification."

On April 8, 2004, Applicants filed a response and substitute sequence listing.

On June 22, 2004, the PTO issued a second "Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures". In the Notice, the PTO indicates that Applicant's response dated April 8, 2004 is not compliant because "[t]here is still no submitted sequence listing for said sequence" on page 15, line 24 of the specification.

On August 31, 2004, Applicants filed a response and substitute sequence listing. Applicant's response dated August 31, 2004 was timely filed (i.e., the deadline was September 4, 2004) and compliant with the rejections indicated by the PTO in the communications dated March 4, 2004 and June 22, 2004.

On December 8, 2004, the PTO issued a "Notice of Abandonment" because the PTO believes that "[t]he response period has expired and the CRF filed is defective for the reasons elaborated in the enclosed defective CRF report." Accordingly, the CRF report indicates that the sequence listing filed by the Applicant on August 31, 2004 is not compliant because the Artificial sequence descriptions of SEQ ID NOS:1-18 are erroneously listed as "Artificial sequence = synthetic peptide".

#### REMARKS

Applicant's response and substitute sequence listing filed on August 31, 2004 was fully response to the Office communications mailed March 4, 2004 and June 22, 2004, because a sequence listing was submitted for the sequence on page 15, line 24 of the specification. The missing sequences are assigned SEQ ID NOS. 109 and 110 in the sequence listing dated August 31, 2004. Applicant also amended the sequence listing to include reference to other sequences found in the application, which were not previously identified in the sequence listing (i.e., see SEQ ID NOS: 111-114) and were not referenced in the Communications of March 4, 2004 and June 22, 2004. Additionally, the Applicant submitted a preliminary amendment to amend the specification to include the use of the newly assigned sequence identifiers in all instances where the specification discusses such sequences. A copy of said preliminary amendment is enclosed herewith for the PTO's convenience.

The Notice of Abandonment issued by the PTO on December 8, 2004 is based on a rejection of the sequence listing, which was not previously brought to the attention of the Applicant.

37 CFR 1.135(c) provides that "[w]hen reply by the applicant is a *bona fide* attempt to advance the application to final action, and is substantially a complete reply to the non-final Office action, but consideration of some matter or compliance with some requirement has been inadvertently omitted, applicant may be given a new time period for reply under § 1.134 to supply the omission."

Thus, the Applicant requests the PTO to withdraw the holding of abandonment of the present application and allow the Applicant a new time period to file a response to the present objections.

In the interest of expediting prosecution in this case, Applicants submit herewith a substitute sequence listing dated January 4, 2005. The substitute sequence listing addresses the objections raised by the Examiner in the Notice of Abandonment. The enclosed sequence listing has been amended to provide that SEQ ID NOS: 1-18 are Artificial sequences with the description "synthetic oligonucleotide". Support for the amendment can be, for example, on page 22, line 17 of the specification as filed.

#### SEQUENCE RULE COMPLIANCE

Along with the present Petition, Applicants file a sequence listing in both paper and computer readable form (CRF) along with a statement that the paper and CRF forms of the sequence listing are the same and do not add new matter to the specification. The entry of the sequence listing, which is in full compliance with the requirements of 37 CFR §1.821 through 1.825, is respectfully requested.

#### CONCLUSION

For the reasons outlined above, the Applicant respectfully requests the withdrawal of the holding of abandonment and the issuance of a Notice to Comply, if necessary, or a first office action on the merits. Additionally, the Applicant requests the Examiner to enter the preliminary amendment dated August 31, 2004.


The present Petition is filed within two months from the date of the Notice of Abandonment and is therefore timely.

Although no fees are believed to be due, the Commissioner is hereby authorized to charge any fees, including any fees for extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney's Docket No. 39754-0531A). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Dated: January 5, 2005

By:

  
Ginger R. Dreger; Reg. No. 33,055

**HELLER EHRMAN WHITE & McAULIFFE LLP**  
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Menlo Park, California 94025  
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Facsimile: (650) 324-0638

SV 2091507 v1  
1/5/05 11:07 AM (39754.0531)



Attorney Docket No.: 39754-0531A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Andrew SAXON, et al.

Application Serial No: 09/770,169

Filed: January 26, 2001

For: **Immunoglobulin Class Switch  
Recombination**

) Confirmation No.: 8085  
)  
) Group Art Unit: 1644  
)  
) Examiner: Schwadron, Ronald B.  
)  
)  
)

**EXPRESS MAIL LABEL NO. EL 977 674 459**

**Date Mailed: August 31, 2004**

**PRELIMINARY AMENDMENT**

MS: Sequence  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

The present communication is responsive to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, mailed on June 22, 2004.

Applicants filed a response to the Office Communication dated March 4, 2004 on April 8, 2004. The Office believes that said response was not compliant because the sequence listing on page 15, line 24 of the specification was not submitted. Therefore, the Office issued a second Notice to Comply on June 22, 2004.

The deadline to respond to the Communications is set three months from the mail date of the original Notice to Comply, dated March 4, 2004. This response is timely filed requesting a Petition for Extension of Time under the provisions of 37 CFR 1.136(a) for three months with necessary fees.

Applicants hereby request entry of the substitute sequence listing submitted concurrently herewith into the specification, starting on a new page, immediately following the claims and the consideration of the following amendments and remarks. The substitute sequence listing, dated August 31, 2004, serves to replace the sequence listing filed on October 29, 2002.

**Amendments to the Specification begin on page 2 of this paper.**

**Remarks begin on page 4 of this paper.**

IN THE SPECIFICATION:

Please replace the paragraph at page 15, line 21 with the following paragraph:

--Several class switch regions (S regions) have been characterized, including the murine S $\mu$ , S $\epsilon$ , S $\alpha$ , S $\gamma_3$ , S $\gamma_1$ , S $\gamma_{2a}$  and S $\gamma_{2b}$  switch regions and human S $\mu$  and S $\gamma$  switch regions (Mills et al., (1995), *supra*.) For example, the murine S $\mu$  region is about 3 kb and can be divided into a 3' region with sequences [(GAGCT) $_n$ GGGGT] $_m$ , [(SEQ ID NO:109) $_n$ SEQ ID NO:110] $_m$  wherein n=1-7 and m=150 (Nikaido et al., *Nature* 292:845-848 (1981)), and a 5' region in which these two pentamers are interspersed with the following heptamer sequence: (C/T)AGGTTG (SEQ ID NO:111) (Marcu et al, *Nature* 298:87-89 (1982)). The human S $\mu$  sequence is different in that the heptamer sequence is distributed throughout the region (Takahashi et al., *Cell* 29:671-679 (1982); Mills et al. (1995) *supra*). All S sequences contain multiple copies of the pentameric sequences GAGCT (SEQ ID NO:109) and GGGGT (SEQ ID NO:110), and the pentamers ACCAG (SEQ ID NO:111), GCAGC (SEQ ID NO:112), and TGAGC (SEQ ID NO:113) are also commonly found in S regions (Gritzmacher, *Crit. Rev. Immunol.* 9:173-299 (1989)). In addition, the foregoing heptameric repeat is also commonly found in native S regions. All these regions/repeats, and similar regions from other murine or human S regions will be referred to as "GC rich" regions or repeats.--

Please replace the paragraph at page 43, line 31 with the following paragraph:

--One characteristic feature of Ig class switch recombination is that deletional recombination between two involved S regions is region specific but site non-specific; i.e. it falls in the category of "illegitimate" recombination (Dunnick et al., *Nucleic Acids Res.* 21:365-372 (1993)). To show that the recombination sites employed following nuclear extract-driven recombination demonstrate this feature, we sequenced the recombination junctions of recombined clones. Thirty-two randomly selected colonies that hybridized to both S $\mu$  and S $\epsilon$  probes from the *in vitro* recombination assay and 17 colonies derived from direct PCR amplification were sequenced. The breakpoints were defined by alignment of the clone sequences with the S $\mu$  and S $\epsilon$  sequences in plasmid p77D3.11. The sequences around the recombination junctions from 10 clones derived from recombination assay and 10 clones from PCR amplification are shown in Figures 13A and 13B, respectively. The homology between S $\mu$  and S $\epsilon$  in these sequence identified clones from both recombination assay and PCR assay varies from a homology of 15 (clone SR.23-10) nucleotides to 0 (e.g., clones

R5.22-10, R5.29-22, SR6.16-13). Clones that contained unmatched sequences in the breakpoint to both S $\mu$  and S $\epsilon$  are also presented (clones R6.4-39, SR9.24-20, and SR28-27). Thus, although clones derived from the *in vitro* recombination assay often share a short stretch of homology for S $\mu$  and S $\epsilon$  in the junctional sites as seen in *in vivo* CSR, homology between S $\mu$  and S $\epsilon$  was not required for switch-region DNA recombination in our system. The frequently observed short homologous stretches between S $\mu$  and S $\epsilon$  at the recombination junctions likely reflect the internal features of the S $\mu$  and S $\epsilon$  constructs used to make p77D3.11, with its tandemly repetitive sequences GGGCT (SEQ ID NO:114), GGGGT (SEQ ID NO:110), and GAGCT (SEQ ID NO:109) densely distributed throughout the S $\mu$  and S $\epsilon$  segments.--

REMARKS

Applicants substitute sequence listing filed on April 8, 2004 was not fully response to the Office communication mailed March 4, 2004, because no sequence listing was submitted for the sequence on page 15, line 24 of the specification. The substitute sequence listing submitted concurrently herewith has been revised accordingly. The missing sequence has been assigned SEQ ID NOS. 109 and 110.

Also, Applicant has added new SEQ ID NOS for the sequences in the paragraph starting on page 15, line 21 and the paragraph starting on page 43, line 31. Accordingly, SEQ ID NOS 111-114 have been added to the sequence listing.

The specification has been amended to include the use of the assigned sequence identifiers in all instances where the description discusses such sequences. The amendments to the specification are of a formal nature and do not add new matter.

SEQUENCE RULE COMPLIANCE

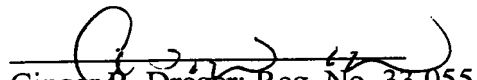
Along with the present Amendment, Applicants file a sequence listing in both paper and computer readable form (CRF) along with a statement that the paper and CRF forms of the sequence listing are the same and do not add new matter to the specification. The entry of the sequence listing, which is in full compliance with the requirements of 37 CFR §1.821 through 1.825, is respectfully requested.

Please charge any additional fees, including any fees for additional extensions of time, or credit overpayment to Deposit Account No. 08-1641, referencing attorney's docket no. 39754-0531A

Respectfully submitted,

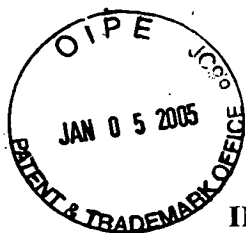
Dated: August 31, 2004

By:

  
Ginger R. Dreger, Reg. No. 33,055

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275 Middlefield Road  
Menlo Park, California 94025  
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Attorney Docket No.: 39754-0531A

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) Group Art Unit: 1644  
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) Examiner: Schwadron, Ronald B.  
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EXPRESS MAIL LABEL NO. EL 977 611 895

Date Mailed: JANUARY 5, 2005

SEQUENCE SUBMISSION STATEMENT

MS: Sequence  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

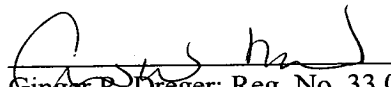
I hereby state that the Sequence Listing information recorded in computer readable form is identical to the written Sequence Listing submitted herewith as required in 37 C.F.R. § 1.821(f) and (g). I further state that these submissions include no new matter.

Please charge any additional fees, including any fees for additional extensions of time, or credit overpayment to Deposit Account No. 08-1641, referencing attorney's docket no. 39754-0531A

Respectfully submitted,

Dated: January 5, 2005

By:

  
Ginger R. Dreger; Reg. No. 33,055

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SV 2091582 v1  
(39754.0531)



39754-0531A saved January 4 2005

SEQUENCE LISTING

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Zhang, Ke

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RECOMBINATION

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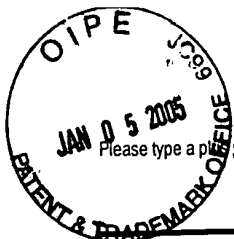
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Group/Art Unit	1644
Examiner Name	SCHWADRON, RONALD B.
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